<u>**Amendments to the Claims:**</u>

This listing of claims will replace all prior versions and listings of claims in the application:

<u>**Listing of Claims:**</u>

1. (Currently amended) A method for determining the biological effect and/or activity of at least one ~~drug and/or~~ pharmaceutical composition, comprising the steps of:

(a) obtaining a biological sample A containing DNA, said biological sample A being from at least one of an individual, a tissue, a cell or another biological material containing DNA, wherein said biological sample A was exposed to said at least one ~~drug and/or~~ pharmaceutical composition;

(b) obtaining a biological sample B containing DNA, said biological sample B being from at least one of an individual, a tissue, a cell or another biological material containing DNA, wherein said biological sample B was not exposed to said at least one ~~drug and/or~~ pharmaceutical composition;

(c) then, analyzing the level of cytosine methylation at chosen sites of the DNA contained in the biological samples A and B;

(d) selecting those of said chosen sites which are differentially methylated between the DNA in biological samples A and B, whereby a knowledge base is generated; and

(e) concluding from ~~the~~ said knowledge base ~~on the~~ <u>a</u> biological effect and/or activity ~~of~~ <u>that</u> said at least one ~~drug and/or~~ pharmaceutical composition ~~of~~ <u>has on</u> said biological sample A

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~~from~~ in step (a) and outputting the conclusion to at least one of a display, a user, a readily accessible memory and a computer on a network.

2. (Previously presented) Method as claimed in claim 1, wherein said biological sample A and/or said biological sample B is obtained by means of a biopsy, by means of an operation on an individual, by means of a dissection, derived from a preserved biological sample, collected from body fluid(s) and/or collected directly from the environment.

3. (Previously presented) Method as claimed in claim 1, characterized in that said biological sample A and/or said biological sample B comprises a eukaryotic and/or prokaryotic cell line, a biopsy sample, blood, sputum, feces, urine, cerebral liquid, tissue embedded in paraffin, tissue derived from eyes, intestine, brain, heart, prostate, kidney, lung, breast or liver, histological samples or a combination thereof.

4. (Previously presented) Method as claimed in claim 1, characterized in that said biological sample A and/or said biological sample B is obtained from biological material of healthy and/or diseased individuals.

5. (Previously presented) Method as claimed in claim 1, characterized in that the biological samples A and B are obtained from the identical individual, the identical tissue, the

identical cell or the identical other biological material.

6. (Currently amended) Method as claimed in claim 5, characterized in that the biological samples A and B are taken before, during and/or after onset of a treatment with said ~~drug and/or~~ pharmaceutical composition.

7. (Previously presented) Method as claimed in claim 1, further comprising the step of isolating DNA from the said samples before analyzing the level of cytosine methylation at chosen sites in said isolated DNA.

8. (Previously presented) Method as claimed in claim 7, characterized in that the isolation of said DNA contained in said biological sample A and/or said biological sample B comprises isolating subcellular compartments, organelles, macromolecular structures and multiprotein complexes, partial or complete preparation of the DNA and/or mRNA of said biological sample A and/or said biological sample B, reverse transcription or partial digestion of the material with an enzyme selected from proteases, RNAses and/or DNAses or combinations thereof.

9. (Previously presented) Method as claimed in claim 1, characterized in that the analysis of the level of cytosine methylation comprises chemical treatment with bisulphite, hydrogen sulphite or disulphite, polymerase chain reaction (PCR), hybridization analyses, sequencing,

mass spectrometry and fluorescent, enzymatic, radioactive, dye and/or antibody labeling.

10. (Previously presented) Method as claimed in claim 1, characterized in that all potential methylation sites of the DNA of said biological sample A and said biological sample B are analyzed.

11. (Previously presented) Method as claimed in claim 1, characterized in that the level of at least two cytosine methylation sites is analyzed in parallel.

12. (Previously presented) Method as claimed in claim 11, characterized in that the level of at least 100 cytosine methylation sites is analyzed in parallel.

13. (Previously presented) Method as claimed in claim 1, characterized in that the methylation sites are located in methylation relevant regions of the DNA of said biological sample A and said biological sample B comprising complete genes and/or promoters, introns, first exons and/or enhancers.

14. (Previously presented) Method as claimed in claim 1, characterized in that the methylation sites are located in methylation relevant regions of genes operatively linked to unwanted side effects of medicaments; cancers; dysfunctions; damages or diseases of the central

nervous systems (CNS); aggressive symptoms or behavioural disorders; clinical, psychological and social consequences of brain injuries; psychotic disorders and disorders of the personality; dementia and/or associated syndromes; cardiovascular diseases; malfunctions or damages, diseases, malfunctions or damages of the gastrointestine; diseases, malfunctions or damages of the respiratory system; injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process; diseases, malfunctions or damages of the skin, muscles, connective tissue or bones; endocrine or metabolic diseases; malfunctions or damages; headache; and sexual malfunctions or combinations thereof.

15. (Previously presented) Method as claimed in claim 14, characterized in that the methylation sites are located in methylation relevant regions of genes operatively linked to leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's disease.

16. (Previously presented) Method as claimed in claim 1, wherein said analyzed methylation sites are disease specific and/or personalized.

17. (Previously presented) Method as claimed in claim 1, characterized in that the selection is dependent upon the result of at least two individual rows of analyses.

18. (Previously presented) Method as claimed in claim 1, characterized in that the selection is generating a knowledge base comprising only one set of selected sites.

19. (Previously presented) Method as claimed in claim 1, characterized in that the selection is generating a knowledge base comprising different classes of selected sites.

20. (Previously presented) Method as claimed in claim 1, characterized in that the selection is at least partially performed automatically by means of a suited automate.

21. (Previously presented) Method as claimed in claim 1, characterized in that at least two sites are selected in parallel.

22. (Previously presented) Method as claimed in claim 21, characterized in that at least 100 sites are selected in parallel.

23. (Previously presented) Method as claimed in claim 1, characterized in that all or a part of the sites of the knowledge base are used for the conclusion.

24. (Previously presented) Method as claimed in claim 1, characterized in that additional information about said biological sample A and/or said biological sample B is used for the conclusion.

25. (Previously presented) Method as claimed in claim 1, characterized in that the conclusion is dependent upon the result of at least two individual rows of analyses.

26. (Previously presented) The method as claimed in claim 1, characterized in that the conclusion is performed by a computer system.

27. (Previously presented) Method as claimed in claim 1, characterized in that steps a) to d) are repeated.

28. (Previously presented) Method as claimed in claim 1, characterized in that identical biological samples, different biological samples or a combination thereof is used in steps a) and/or b).

29. (Previously presented) Method as claimed in claim 1, characterized in that steps c) to d) are repeated.

30. (Previously presented) Method as claimed in claim 1, characterized in that said method is repeated at least 5 to 50 times.

31. (Previously presented) Method as claimed in claim 1, characterized in that said method is at least partially performed by means of a suited automate.

Claims 32-34 (Canceled).

35. (Withdrawn) Biologically effective and/or active drug, chemical substance and/or pharmaceutical composition, obtained according to a method according to claim 1.

36. (Withdrawn) Use of a biologically effective and/or active drug, chemical substance and/or pharmaceutical composition according to claim 35 for the treatment of a disease and/or medical condition.

37. (Withdrawn) Use according to claim 36, wherein said disease and/or medical condition is related to unwanted side effects of medicaments, cancers, dysfunctions, damages or diseases of the central nervous system (CNS), aggressive symptoms or behavioral disorders, clinical, psychological and social consequences of brain injuries, psychotic disorders and

disorders of the personality, dementia and/or associated syndromes, cardiovascular diseases, malfunctions or damages, diseases, malfunctions or damages of the gastrointestine, diseases, malfunctions or damages of the respiratory system, injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process, diseases, malfunctions or damages of the skin, muscles, connective tissue or bones, endocrine or metabolic diseases, malfunctions or damages, headache, and sexual malfunctions or combinations thereof.

38. (Withdrawn) Use according to claim 37, wherein said disease and/or medical condition is leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's disease.

39. (Withdrawn) A method for the treatment of a disease and/or medical condition, comprising

a) determining at least one biologically effective and/or active drug, chemical substance and/or pharmaceutical composition by means of a method according to claim 1; and

b) providing a treatment for said disease and/or medical condition comprising application of said at least one biologically effective and/or active drug, chemical substance and/or

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pharmaceutical composition to a patient in need.

40. (Withdrawn) Method according to claim 39, wherein said specific treatment is disease and/or patient specific.

41. (Withdrawn) A method according to claim 39 wherein said disease and/or medical condition is selected from treatment of unwanted side effects of medicaments; cancers; dysfunctions, damages or diseases of the central nervous system (CNS); aggressive symptoms or behavioral disorders; clinical, psychological and social consequences of brain injuries; psychotic disorders and disorders of the personality; dementia and/or associated syndromes; cardiovascular diseases; malfunctions or damages, diseases, malfunctions or damages of the gastrointestine; diseases, malfunctions or damages of the respiratory system; injury, inflammation, infection, immunity and/or reconvalescence, diseases, malfunctions or damages as consequences of modifications in the developmental process; diseases, malfunctions or damages of the skin, muscles, connective tissue or bones; endocrine or metabolic diseases; malfunctions or damages; headache; and sexual malfunctions or combinations thereof.

42. (Withdrawn) A method according to claim 39 wherein said disease is selected from leukemia, head and neck cancer, Hodgkin's disease, gastric cancer, prostate cancer, renal cancer, bladder cancer, breast cancer, Burkitt's lymphoma, Wilms tumor, Prader-Willi/Angelman

syndrome, ICF syndrome, dermatofibroma, hypertension, pediatric neurobiological diseases, autism, ulcerative colitis, fragile X syndrome, and Huntington's disease.

43. (Currently amended) A method for determining the biological effect and/or activity of at least one ~~drug and/or~~ pharmaceutical composition, comprising the steps of:

(a) obtaining a biological sample A containing DNA, said biological sample A being from at least one of an individual, a tissue, a cell or another biological material containing DNA, wherein said biological sample A was exposed to said at least one ~~drug and/or~~ pharmaceutical composition;

(b) obtaining a biological sample B containing DNA, said biological sample B being from at least one of an individual, a tissue, a cell or another biological material containing DNA, wherein said biological sample B was not exposed to said at least one ~~drug and/or~~ pharmaceutical composition;

(c) then, analyzing the level of cytosine methylation at chosen sites of the DNA contained in the biological samples A and B, wherein said analyzing comprises chemical treatment of each of biological sample A and biological samples B with at least one of bisulfite, hydrogen sulfite or disulfite;

(d) selecting those of said chosen sites which are differentially methylated between the DNA in biological samples A at step (a) and B at step (b), whereby a knowledge base is generated; and

(e) concluding from ~~the~~ said knowledge base ~~on the~~ a biological effect and/or activity ~~of~~ that said at least one ~~drug and/or~~ pharmaceutical composition ~~of~~ has on said biological sample A ~~from~~ in step (a) and outputting the conclusion to at least one of a display, a user, a readily accessible memory and a computer on a network.

44. (Previously presented) The method as claimed in claim 43 wherein said biological samples A and B are obtained from the same individual, the same tissue, the same cell or the same other biological material containing DNA.